

Remarks

Claims 3-18 are in the case. Claims 1-2 were previously cancelled. No claim amendments are requested at this time. Claims 3-18 stand rejected. For the following reasons, reconsideration is respectfully requested. Because applicant's previous claim amendments resulted in the Examiner's reliance on prior art that had not been previously cited, applicant has elected to file a request for continued examination.

Double Patenting Rejection

In response to the obviousness-type double patenting rejection, applicant submits a terminal disclaimer.

Claim Rejections – 35 USC § 103(a)

Claims 3-18 are rejected under 35 USC 103(a) as being unpatentable over Reiley et al. (U.S. 6,575,919) in view of Sorenson et al. (US2002/0123723) and further in view of Kerr et al. (U.S. 2003/0036762). The Examiner takes the position that Reiley discloses all of the elements of the claimed invention with the exception of a plurality of ports on the tubular delivery member and a bone graft material including calcium sulfate. With regard to the plurality of ports, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ports on the tubular delivery member utilized in the method of Reiley et al., as taught by Sorenson et al., to uniformly distribute a volume of treatment fluid to a larger area. With regard to the bone graft material, the Examiner concludes that it would have been obvious to use a calcium sulfate material, as taught by Kerr et al., in the method of the combination of Reiley et al. and Sorensen et al.

It is respectfully submitted that a prima facie of obviousness has not been established. The present application is directed primarily to solving the following problems, which are identified in applicant's discussion of the prior art:

Since the only opening for delivery of the bone graft material is the axial port, the prior art needle has the disadvantages of: (1) being unable to deliver bone graft material when the axial port abuts bone or other tissues, (2) not being able to radially inject bone graft material, and (3) requiring undesirable excessive force to eject bone graft material through the axial port.

As far as the applicant can determine, the cited references do not address the foregoing problems, much less suggest solutions to these problems. Conspicuously missing from the cited references is any suggestion, teaching or motivation to use a needle having a radial port to deliver a bone graft material. Of the three cited references, only the Sorensen reference teaches the use of a needle having radial ports. However, as far as the applicant can determine, Sorensen is concerned only with the discharge of fluids through the syringe. Nothing in Sorensen suggests the use of an axially and radially ported needle to discharge a paste or a bone graft material.

Of the three cited references, only Kerr mentions the use of calcium sulfate bone paste materials. However, as discussed in applicant's specification, the delivery of calcium sulfate bone graft pastes through syringes is known, and indeed applicant is a leading manufacturer and supplier of such pastes. Kerr is directed to solving a different problem than that addressed by the present application, namely the delivery of highly viscous materials through an axial port. Kerr framed the problem as follows:

However, especially with highly viscous or solid, yet pliable cement compositions, it is often difficult with a standard push-type syringe to generate the pressure needed to express the material through the syringe outlet opening by exerting pressure on the syringe plunger in an axial direction. Another serious problem is that once sufficient pressure is applied to the plunger, it is difficult to precisely control the amount of material expelled through the outlet opening of the barrel, resulting in extraosseous (i.e., outside the bony cavity) flow.

(Kerr, ¶[0003]). Kerr's solution to solving the problem is to provide a threaded syringe barrel and plunger combination. As Kerr explains:

"Those skilled in the art will appreciate that significant pressures can be generated within barrel 12 as plunger 16 is advanced into barrel 12 by rotating plunger 16 relative to barrel 12, particularly when highly viscous or solid, yet pliable bone cement compositions are situated within barrel 12. In that regard, in a preferred embodiment the mechanical advantage provided through the use of the threaded plunger is preferably about 5 to 1.

(Kerr, ¶[0038]). Although Kerr describes the configuration of the distal end of the syringe barrel and the axial port, and makes reference to radial aspects of the device, Kerr does not identify the problems raised in applicant's specification, nor suggest their solution.

As mentioned above, applicant is a leading manufacturer and supplier of calcium sulfate pastes. While researching methods of delivering calcium sulfate bone graft pastes, applicant conceived of delivering such a paste in the manner embodied in the claims. By combining three SN 10/678,701

prior art references to provide the steps of the claimed method, it is respectfully suggested that applicant's disclosure is being used to reconstruct applicant's claimed invention.

The present case is similar to *In re Dembiczak*, 175 F.3d 994, 50 USPQ.2d 1614 (Fed. Cir. 1999). In *In re Dembiczak*, the claims were drawn to a generally round, orange plastic trash bag with a jack o'lantern face imprinted thereon. The claims were initially rejected as obvious in view of conventional trash bags in combination with a reference showing a jack o'lantern face on an orange paper bag stuffed with newspapers. However, the Federal Circuit reversed, finding that there was no suggestion or motivation to combine the cited references. In establishing the nonobviousness of Dembiczak's invention, the Federal Circuit noted the following concerns about application of the "suggestion to combine" requirement:

Our analysis begins in the text of section 103 quoted above, with the phrase 'at the time the invention was made.' For it is this phrase that guards against entry into the 'tempting but forbidden zone of hindsight,' see *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 U.S.P.Q. (BNA) 90, 98 (Fed. Cir. 1985), overruled on other grounds by *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2D (BNA) 1097 (Fed. Cir. 1998), when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983). *Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.'* *Id.*

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

Id., 175 F.3d at 998-999 (emphasis added); see also MPEP §§ 2142, 2143.01.

In this case, as in *Dembiczak*, the cited references lack the necessary suggestion to combine the references in the manner of the claimed method. In the absence of a suggestion, teaching, or motivation to modify Reiley's method to include Sorenson's radial openings, and in SN 10/678,701

the absence of a suggestion, teaching or motivation to further modify Reiley/Sorenson to use a calcium sulfate bone graft paste according to Kerr, it is respectfully suggested that a *prima facie* case of obviousness has not been established.

Conclusion

Applicant suggests claims 3-18 are now in a condition for allowance, and respectfully requests issuance of a notice of allowance. If the Examiner concludes that a telephone interview would facilitate examination of this application, undersigned would welcome such a conference. It is believed that this response has been filed timely and that no extension of time is required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,



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